

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lee et al.

Appl. No.: 09/837,297

Filing Date: April 19, 2001

Title: Hepatitis B Virus Vectors For Gene  
Therapy

Art Unit: 1646

Examiner: To Be Assigned

Atty. Docket: 0257-0003

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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith.

☒1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

☐2. The Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

☐a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 (c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

☐c. Attached is our check no. \_\_\_\_\_ in the amount of \$\_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

☐3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicants hereby petition that the Information Disclosure Statement be considered. Attached is our check no. \_\_\_\_\_ in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(i)(1).

☐a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

☐b. I hereby certify that no item of information on this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

☐4. Relevance of the non-English language document(s) is discussed in the present specification. See pages \_\_\_\_\_ of the specification of the present application.

☐5. The document(s) was/were cited in a corresponding foreign application. ☐ A copy of a search report issued in the foreign application is attached. ☐ An English language version of the foreign search report is attached for the Examiner's information. M.P.E.P. § 609 (A)(3).

☐6. A concise explanation of the relevance of the non-English language document(s) ☐ is attached hereto or ☐ appears below.

- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).
- ☐ 9. Other: .

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0622

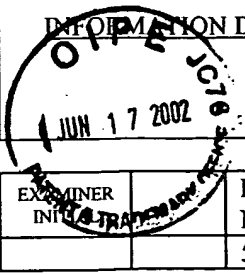
Respectfully submitted,

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FORM PTO 1449		ATTY. DOCKET NO. 0257-0003		APPLICATION NO. 09/837,297		
INFORMATION DISCLOSURE STATEMENT 		APPLICANT(S) Lee et al				
		FILING DATE April 19, 2001		GROUP 1646		
		U.S. PATENT DOCUMENTS				
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	5,981,274	11/9/99	Tyrrell et al			
FOREIGN PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						<input type="checkbox"/> Yes <input type="checkbox"/> No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

		Anderson, W., <i>Human Gene Therapy</i> , <u>Science</u> , 256: 808-13 (1992)
		Ausubel, F. et al. eds. <i>Current Protocols in Molecular Biology</i> , Wiley and Sons, New York, Suppl. 48 (1995)
		Chaisomchit, S. et al., <i>Development of replicative and nonreplicative hepatitis B virus vectors</i> , <u>Gene Therapy</u> , 4: 1330-40 (1997)
		Chiang P. et al., <i>Characterization of a cis Element Required for Packaging and Replication of the Human Hepatitis B Virus</i> , <u>Virology</u> , 186: 701-11 (1992)
		Condreay, L. et al., <i>Replication of DHBV Genomes with Mutations at the Sites of Initiation of Minus- and Plus-Strand DNA Synthesis</i> , <u>Virology</u> , 188: 208-16 (1992)
		Crystal, R., <i>Transfer of Genes to Humans: Early Lessons and Obstacles to Success</i> , <u>Science</u> , 270: 404-10 (1995)
		Douglas, J. et al., <i>A system for the propagation of adenoviral vectors with genetically modified receptor specificities</i> , <u>Nature Biotechnology</u> , 17: 470-75 (1999)
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		Ganem, D. et al., <i>Hepadnaviridae and Their Replication</i> , <u>Fundamental Virology</u> , 3 <sup>rd</sup> ed., 1199-1233 (1996)
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		Ho, T., et al., <i>Effects of Genomic Length on Translocation of Hepatitis B Virus Polymerase-Linked Oligomer</i> , <u>Journal of Virology</u> , 74: 9010-18 (2000)
		Jeong, J. et al. <i>Evidence that the 5'-end Cap Structure Is Essential for Encapsidation of Hepatitis B Virus Pregenomic RNA</i> , <u>Journal of Virology</u> , 74: 5502-08 (2000)
		Junker-Niepmann, M. et al., <i>A short cis-acting sequence is required for hepatitis B virus pregenome encapsidation and sufficient for packaging of foreign RNA</i> , <u>The EMBO Journal</u> , 9: 3389-96 (1990)
		Loeb D. et al., <i>Mutations within DR2 Independently Reduced the Amount of both Minus- and Plus-Strand DNA Synthesized during Duck Hepatitis B Virus Replication</i> , <u>Journal of Virology</u> , 70: 8684-90 (1996)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO 1449	ATTY. DOCKET NO. 0257-0003	APPLICATION NO. 09/837,297
INFORMATION DISCLOSURE STATEMENT	APPLICANT(S) Lee et al	
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U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

		Loeb D. et al., <i>Sequence Identity of the Terminal Redundancies on the Minus-Strand DNA Template Is Necessary but Not Sufficient for the Template Switch during Hepadnavirus Plus-Strand DNA Synthesis</i> , <u>Journal of Virology</u> , 71: 152-60 (1997)
		Loeb D. et al., <i>Sequence-independent RNA cleavages generate the primers for plus strand DNA synthesis in hepatitis B viruses: implications for other reverse transcribing elements</i> , <u>The EMBO Journal</u> , 10: 3533-540 (1991)
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		Nassal, M. et al., <i>A Bulged Region of the Hepatitis B Virus RNA Encapsidation Signal Contains the Replication Origin for Discontinuous First-Strand DNA Synthesis</i> , <u>Journal of Virology</u> , 70: 2764-73 (1996)
		Nassal, M. et al., <i>Hepatitis B Virus Replication- an update</i> , <u>Journal of Viral Hepatitis</u> , 3: 217-26 (1996)
		Nassal, M. et al., <i>Translational Inactivation of RNA Function: Discrimination against a Subset of Genomic Transcripts during HBV Nucleocapsid Assembly</i> , <u>Cell</u> , 63: 1357-63 (1990)
		Pollack, J. et al., <i>Site Specific RNA Binding by a Hepatitis B Virus Reverse Transcriptase initiates Two Distinct Reactions: RNA Packaging and DNA Synthesis</i> , <u>Journal of Virology</u> , 68: 5579-87
		Protzer, U. et al., <i>Interferon gene transfer by a hepatitis B virus vector efficiently suppresses wild-type virus infection</i> , <u>Proc. Natl. Acad. Sci.</u> , 96: 10818-23 (1999)
		Sambrook et al., <i>Molecular Cloning: A Laboratory Manual</i> , Cold Spring Harbor Press 3 <sup>rd</sup> ed, (2001)
		Seeger, C. et al., <i>Identification of a Signal Necessary for Initiation of Reverse Transcription of the Hepadnavirus Genome</i> , <u>Journal of Virology</u> , 65: 5190-95 (1991)
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		Staprans, S. et al., <i>Mutations Affecting Hepadnavirus Plus-Strand DNA Synthesis Dissociate Primer Cleavage from Translocation and Reveal the Origin of Linear Viral DNA</i> , <u>Journal of Virology</u> , 65: 1255-62 (1991)

EXAMINER	DATE CONSIDERED
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FORM PTO 1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

0257-0003

APPLICATION NO.

09/837,297

APPLICANT(S)

Lee et al

FILING DATE

April 19, 2001

GROUP

1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						<input type="checkbox"/> Yes <input type="checkbox"/> No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

			Wang, G. et al., <i>Novel Mechanism for Reverse Transcription in Hepatitis B Virus</i> , <u>Journal of Virology</u> , 67: 6507-12 (1993)
			Wang, G. et al., <i>The Reverse Transcriptase of Hepatitis B Virus Acts As A Protein Primer for Viral DNA Synthesis</i> , <u>Cell</u> , 71: 663-70 (1992)
			Yang, Y. et al., <i>Clearance of Adenovirus-Infected Hepatocytes by MHC Class I-Restricted CD4<sup>+</sup> CTLs In Vivo</i> , <u>The Journal of Immunology</u> , 155: 2564-70 (1995)
			Yen, T., <i>Posttranscriptional Regulation of Gene Expression in Hepadnaviruses</i> , <u>Virology</u> , 8: 319-26 (1998)

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